

K081322

JUN 18 2008

*\* This document can be copied and submitted to interested parties as required by 21 CFR 807.92.*

**510(k) Summary of Safety and Effectiveness**

**Submitter: International Regulatory Consultants**

**For: Shanghai Chenguang Medical Technologies Co., Ltd**

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**E-mail: stzhang@shanghaicg.net**

**Company Contact: Songtao Zhang**

**Date Summary Prepared: April 5, 2008**

**Device Name**

**Trade Name: Pediatric Head and Spine Array Coil1.5T 8ch**

**Common Name: Pediatric Head and Spine Array Coil**

**Classification Name: 892.1000 Magnetic Resonance Diagnostic Device**

**Classification: Class II**

**Predicate Devices (Legally Marketed Devices)**

A predicate device for the 0100140201 Pediatric Head Spine coil 1.5T is the PHS-63 Pediatric Head Spine Coil, manufactured by MRI Devices Corporation and cleared under K003655.

**Device Description**

The Model 0100140201 Pediatric Head and Spine Array Coil1.5T 8ch consists is a single unit with eight coils. Four coils are in the head area and four coils reside in the back portion of the device. This forms a 8-channel phased array, receive-only coil, used for obtaining diagnostic images of head and spine of a pediatric body in magnetic resonance imaging systems. Combination of back part and head part forms an 8-channel phased array, receive-only coil, used for

obtaining diagnostic images of the head and spine in magnetic resonance imaging systems. These images when interpreted by a trained physician, yielding information that may assist in diagnosis.

#### **Intended Use**

The Pediatric Head-Spine Coil is a receive-only coil, used for obtaining diagnostic images of pediatric head and spine in magnetic resonance imaging systems. These images when interpreted by a trained physician, yielding information that may assist in diagnosis.

Anatomic regions: Head-Spine of a pediatric body.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 18 2008**

Shanghai Chenguang Medical Technologies  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

Re: K081322

Trade/Device Name: Magnetic Resonance Diagnostic Device, Model 0100140201, Pediatric  
Head-Spine Coil

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: MOS

Dated: June 2, 2008

Received: June 3, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

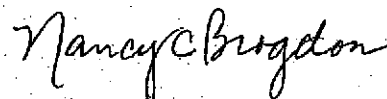
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name:

Magnetic Resonance Diagnostic Device, Model 0100140201, Pediatric Head-Spine Coil

Indications for Use:

The Pediatric Head-Spine Coil is a receive-only coil, used for obtaining diagnostic images of pediatric head and spine in magnetic resonance imaging systems. This coil is designed to be used in a Philips Achieva MRI 1.5T system. These images, when interpreted by a trained physician, yield information that may assist in diagnosis.

Prescription Use ☒  
(Part 21 CFR 801  
Subpart D)

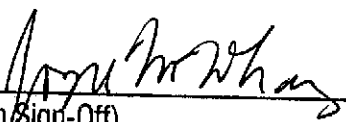
AND/OR

Over-The-Counter  
Use \_\_\_\_\_  
(21 CFR 801 Subpart  
C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

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- End of Section -

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